

DEC 12 2005

**8.0 Premarket Notification 510(k) Summary**  
[As required by section 807.92(c)]

K050817

**Applicant:** Michael J. Morris  
R2 Diagnostics, Inc.  
412 South Lafayette Blvd.  
South Bend, IN 46601  
USA

**Contact:** Dr. Peggy S. Carter  
R2 Diagnostics, Inc.  
412 South Lafayette Blvd.  
South Bend, IN 46601  
TEL: (574) 288-4377  
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**Date:** October 25, 2005

**Trade Name:** R2 Diagnostics T-Tek

**Common Name:** Thrombin time test

**Classification Name:** Test, thrombin time  
(per 21 CFR section 864.7875)

**Comparison Device:** STA Thrombin, K884384

**Description of the Device and Intended Use**

The T-Tek Thrombin Time Reagent contains a lyophilized thrombin reagent, for use in the quantitative determination of thrombin time in citrated human plasma. The thrombin time test is a one-stage quantitative clotting test performed on citrated plasma samples in the general patient population. The thrombin time test is used to detect disorders of fibrinogen. The T-Tek, Thrombin Time Reagent should only be used in an appropriate clinical laboratory by qualified laboratory professionals. The test may be performed manually, or using semi-automated and automated coagulation analyzers.

### **Summary of Substantial Equivalence Comparisons**

R2 Diagnostics T-Tek Thrombin Time Reagent is substantially equivalent in intended use and performance to STA Thrombin 10. Both the predicate device and the proposed product are formulated to determine thrombin time in citrated plasma. In correlation studies normal and abnormal patient plasma, as well as plasma samples from patients undergoing heparin therapy, were tested using both reagents. Comparison of data from thrombin time testing at two sites and on two different instrument types yielded correlation coefficients of  $r^2 = 0.801$  (photo-optical), slope = 0.848, intercept = 3.466 and  $r^2 = 0.800$  (mechanical), slope = 1.204, intercept = -4.904. Within-run and between-run precision studies were also performed and CV's of less than 3% were obtained for the proposed device. CV's of less than 3% are reported for the predicate device in the manufacturers Instructions for Use.

### **Conclusion: Substantial Equivalence Statement**

In Summary, the similar intended use, technological characteristics and the performance data provided in this premarket notification demonstrate that R2 T-Tek Thrombin Time Reagent is substantially equivalent to (Diagnostics Stago) American Bioproducts Co., STA Thrombin 10.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

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Dr. Peggy S. Carter  
Director, Product Development  
R2 Diagnostics, Inc.  
412 South Lafayette Blvd  
South Bend, IN 46601

Re: k050817  
Trade/Device Name: T-Tek  
Regulation Number: 21 CFR 864.7875  
Regulation Name: Thrombin time test  
Regulatory Class: Class II  
Product Code: GJA  
Dated: October 26, 2005  
Received: November 1, 2004

Dear Dr. Carter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

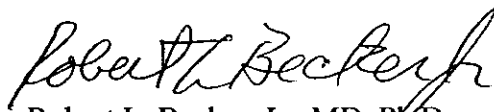
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 —

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

A handwritten signature in black ink, reading "Robert L. Becker, Jr." with a stylized flourish at the end.

Robert L. Becker, Jr., MD, Ph.D  
Director

Division of Immunology and Hematology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

## 6.0 Indications for Use

510(k) Number (if known): K050817

Device Name: T-Tek

Indications for Use:

### Statement of Indications for Use

The T-Tek Thrombin Time Reagent contains a lyophilized thrombin reagent, for use in the quantitative determination of thrombin time in citrated plasma. The thrombin time test is a one-stage quantitative test performed on diluted plasma samples in the general patient population. The thrombin time test is used to detect disorders of fibrinogen. The T-Tek, Thrombin Time Reagent should only be used in an appropriate clinical laboratory by qualified laboratory professionals.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

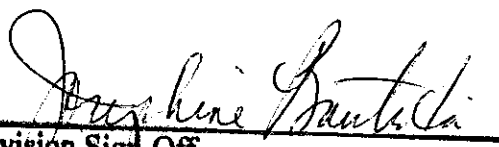
Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Posted November 13, 2003)

  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K 050817